PATENTS IN GENES

Prepared for

The Canadian Biotechnology Advisory Committee Project Steering Committee on Intellectual Property and the Patenting of Higher Life Forms

By

E. Richard Gold

December 2000

This publication is also available electronically on the World Wide Web at the following address: cbac-cccb.ca

This publication is also available in alternative formats on request.
Contact the Canadian Biotechnology Advisory Committee (CBAC) at the numbers listed below.

For additional copies of this publication, please contact the:

Canadian Biotechnology Advisory Committee (CBAC)
235 Queen Street
7th Floor - Room 744B
Ottawa ON K1A 0H5

Tel: (613) 957-7715
Toll free : 1 866 748-CBAC (2222)
TTY : 1 866 835-5380
Fax: (613) 946-2847
Web: cbac-cccb.ca
E-mail: info@cbac-cccb.ca

PATENTS IN GENES

By E. Richard Gold[*]
Assistant ProfessorFaculty of LawThe University of Western Ontario

Senior FellowThe Einstein Institute for Science, Health & the Courts

Research Associate
Health Law Institute, University of Alberta

[*]The opinions expressed in this paper belong to the author and do not necessarily represent the views of the Einstein Institute for Science, Health & the Courts or of its directors.

INTRODUCTION

Over the past year, the first phase of the Human Genome Project came to an end. By the summer of 2000, we had a fairly complete and accurate listing of all the genes in a typical human being. Apart from the tremendous impact that this knowledge will have on health care, it also represents a patent rush where both private and public institutions vie to gain temporary control, through patents, over the use and reproduction of genetic information. This paper examines the patentability of genes, the tests used by patent offices to award patents, and the policy issues that arise from gene patenting, particularly on the larger question of the patenting of higher life forms.

EXECUTIVE SUMMARY

By the summer of 2000, the Human Genome ProjectBthe international effort to sequence all the DNA in a typical human beingBproduced good quality sequences of all the genes in our bodiesy. Along the way to sequencing all human DNA, many private and public institutions have attempted to gain control over the next, and more profitable, research stages in which researchers will use knowledge of human DNA to create commercial products and services. They attempt to do so through gene patenting.

Genes, as they occur in our bodies, are not patentable. But this is not really the interesting point. Genes can only be used for research or commercial purposes once isolated and purified. Isolated genes constitute something that can potentially be patented. This is because, genes never come neatly in isolated and purified form. These genes can be patented provided that they are new, non-obvious, and useful.

Many isolated and described genes will be new, since they were not previously known, and not obvious, since their existence as genes would not have been obvious to an ordinary researcher. The big question is whether the isolated genes are useful. In the United States, a gene is considered useful if either someone skilled in the relevant art would immediately recognize its utility or, alternatively, if the gene has a specific, substantial, and credible utility. This is a moderate to high standard of utility. The general utility standard in Europe (other than for human genes in respect of which it is similar to that of the United States) is that an invention can be made or have some industrial use. The standard is stated to be low. Canada appears to apply a standard similar to that described in the United States. In Canada, an invention must have an actual, ultimate utility in order to meet the utility standard.

The mere fact that a gene is new, non-obvious, and useful does not automatically lead to a patent. The inventor must first file a patent application which, by the time a patent is issued, will cost $10,000 or more per country. Some countries limit the number of genes that may be included in a single application in order to prevent people from over-applying for patent protection. The United States limits the number to ten independent genes while the European Patent Office limits the number to one. Canada has no limits.

In addition, some patent offices can withhold a patent despite an invention meeting the novelty, non-obviousness, and utility requirements if the commercial exploitation of the patent would violate public order[1] or morality. European and Asian patent offices have this power; Canadian, American, and Australian patent offices do not. All countries agree that public order and morality are

[1]The technical term for this concept is Aordre public@ which, in English, translates into public order or public policy. Although international tribunals have, on occasion, given a very wide meaning to this phraseBto include anything that a government believes to be good public policyBinternational tribunals have given the phrase a considerably narrower interpretation with respect to international agreements touching on patents. See, for example, European Patent Office Boards of Appeal, *Plant Genetic Systems Dec. T356/93 of 21 February 1995,* O.J. EPO (1995) at 545. In the context of international patent conventions, Aordre public@ generally means the protection of public security, the physical integrity of individuals as part of society, and the protection of the environment.

important; they simply differ as to whether these concerns ought to be addressed within patent law or through specific laws and regulations.

Patenting genes and DNA sequences gives rise to many public policy concerns. These include concern that those who provide samples of their DNA (and perhaps their blood relatives) have given fully informed consent; that the benefits and risks arising out of the human, animal, or plant gene patents isare equitably shared; that an appropriate balance is struck between preventative and therapeutdic research; that an appropriate balance is struck between food needs in the developing world and the developed world; that the environment be protected; and that inventors have an adequate financial incentive to invent without creating so many patents that future researchers find it impossible to undertake the next stage of research.

The question of whether plants and animals are patentable in Canada is currently before the courts. By controlling the use and sale of a patented gene, the patent owner can also effectively prevent others from creating a genetically-modified plant or animal using that gene. Once a genetically-modified plant or animal is created and is purchased by someone, the patent over the underlying gene could not be used to prevent further reproduction of that animal or plant. If, however, the gene patent holder licenses the use of the plant or animal to farmers rather than selling it, he or she can place conditions on the use of the plant or animal, such as that the farmer will not reproduce it.

While commentators have suggested ways both within and external to patent law to address the policy concerns arising out of gene patenting, so far none of these suggestions has been implemented.

PATENTS IN GENES

Almost every cell in the humanour body contains DNA. DNA is the molecule that holds the code for each and every protein that our bodies use. Our cells transform the code contained in the DNA into proteins (each packet of DNA that codes for a particular protein is called a gene) which in turn are the workhorses of the cell. These proteins do everything from helping us to get energy, to building bones, to removinge toxins, to determininge our hair and eye colour. By working together, these proteins control the internal workings of our bodies and our interactions with the outside environment.

Given both the ubiquity and role of DNA in our bodies, many countries, Canada included, are participating in the largest single public scientific effort of the late 20th and early 21st century: the determination of the entire sequence of DNA in a typical human being. That effort has come to fruition this year as both public institutions and private enterprise have recently completed a rough draft of the DNA list.

Along the way to sequencing all human DNA—called the human genome—many private and public institutions have attempted to gain control over the next, and more profitable, research stages in which researchers will use knowledge of human DNA to create commercial products and services ranging from pharmaceuticals, to diagnostic tests, to new therapies, to artificial reproductive techniques. They gain this control by patenting genes and portions of genes that they believe will lead to these final products.

Patenting Genes and Gene Sequences

It may surprise some that one can patent a gene or a portion of a gene. After all, each one of us has in the vicinity of 75,000 to 100,000 genes in almost every cell of his or her body. These genes came from our parents and from their parents before them. Since patents are designed to encourage new invention, in what way can we consider these genes to be new?

The simple response to this question about the newness of genes is that genes, as they occur in our bodies, are not patentable. After all, if they were, no one would be permitted to grow new skin let alone have children. Genes, as they exist naturally within our bodies, cannot be patented for the simple reason that they have been around for a very long time. But this is not really the interesting question. After all, it is not much use to anyone but the particular individual involved to have ownership of one gene mixed up with 75,000 to 100,000 others in the middle of cells all over that person=s body. Genes can only be used for research or commercial purposes once isolated and purified.

Isolated genes**B**genes that have been removed from the body and copied many, many times**B**constitute something that can potentially be patented if they otherwise meet the criteria for patentability described below. This is because, in all the eons that have passed since our genes came into existence, they have never come neatly in isolated and purified form. This is one of the hallmarks of an invention: that it would not have existed but for human intervention.

In fact, anything takenisolated from a human, animal, or plant and put into isolated form can potentially be patented. This means that sequences of DNA smaller than an entire gene**B**even a sequence of as low as 15 codes, called an expressed sequence tag (EST)**B**as well as proteins and other molecules isolated from living organisms can be patented provided that they otherwise fit the

requirements of patent law. These requirements are that the isolated material be new, non-obvious, and useful and that it be sufficiently described. This is the same test that applies to all innovation from mousetraps to superconducting wires. The mere fact that the Ainvention@ is a distilled version of what nature produces does not disqualify the invention from being patented.

While some have argued that what really has been invented is the method by which the DNA sequence is isolated and not the DNA sequence itself[2]Bthat is, how we got the DNA to be in isolated form rather than the DNA itself in isolated formBpatent offices around the world, including in Canada, continue to grant patents on genes and DNA sequences. In fact, virtually every major industrial country has granted patents not only on genes but on proteins and other material isolated from the human body.[3] Currently, patent applications over short DNA sequences are going through the patent

---

[2]See, for example, R.P. Merges & R.R. Nelson, AOn the Complex Economics of Patent Scope@ (1990) 90 Colum. L. Rev. 839.

[3]Despite the June 2000 statement by the French Minister of Justice raising doubts about the patentability of human genes in France, patents over human genes currently exist in France. It is possible, if it were to accept the Minister=s arguments, that a French Court could find that these patents are invalid in France should these patents be challenged. This is doubtful, however, given *Directive 98/44 of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions*, O.J. Legislation (1998) No L213 at 13 .

process and have already been awarded in the United States. There is nothing in patent law that would prevent, in theory, these ESTs from being patented provided that the EST otherwise meets patenting criteria.

Patent Criteria

We grant patents in inventions that are new, non-obvious, and useful. Something is new if it has not been described before in public. An invention that is non-obvious means that it would not have been entirely obvious to a researcher in the field to have created the invention taking into account the current state of knowledge in that field. By useful, we mean that the invention has some practical application.

A gene, whether of human origin or otherwise, or a DNA sequence can thus be patented in isolated form if that gene or sequence has not been described before, the isolation of that gene or sequence was not obvious, and that the gene or sequence has some utility. Given that the Human Genome Project has given rise to a vast amount of new information about human genes and DNA, the genes that are sought to be patented will likely qualify as being new. Similarly, since it is difficult to identify a particular gene within the vast amounts of DNA that exists in a cell, a gene or gene sequence is also likely to meet the non-obviousness requirement. While it may be obvious to use well-known techniques to isolate DNA sequences in general, it is likely not obvious that it is worthwhile to isolateing a particular DNA sequence.. The real question thus becomes whether the genes and gene sequences are sufficiently useful to be patentable.

The Utility Standard

Utility can be measured in many ways. A CD player is useful to play music, but is also useful as a paperweight or as a doorstop. Given the wide variety of uses to which an invention could, in theory, be put, we can apply the utility standard either restrictively or liberally. The United States and Canada take a more restrictive approach to utility than do the Europeans.

Up Uuntil recently, the United States has been criticized for the lack of rigour with which it has applied the utility requirement to biotechnological inventions. In order to respond to these criticisms and to better apply rules set down by the Unites States Supreme Court in 1966,[4] the United States Patent and Trademark Office recently issued revised guidelines on how it will apply the utility standard to biotechnological inventions. These guidelines state that an invention can meet the utility requirement by possession a specific, substantial, and credible utility. This can be demonstrated in one of two ways.

The first way in which an invention can be shown to be useful is where someone with knowledge of the area would immediately recognize that the invention is useful. That is, where the utility of the invention is so clear that anyone in the field would see it, the invention is deemed to be useful. Many gene-based inventions will not meet this test since people in the field will not know, in advance, of

[4] *Brenner* v. *Manson*, 383 U.S. 519 (1966).

the specific ways in which the invention can be used. In this case, the invention would need to qualify as useful in the second way.

The second way for an invention to be demonstrated as useful is if the inventor shows that the invention possession each of a specific, a substantial, and a credible utility. To have a specific utility, the invention must be useful in a way that is unique to it. So, for example, while many CD players can play music, the claimed CD player has the special ability to better resist outside vibration. For an invention to have a substantial utility, it must have a real world, commercial utility. Neither basic research nor a general statements that the invention may be useful in curing disease counts as a substantial utility, the first because it is not a commercial utility and the second because there is no substantive reason given why the invention should be any better than anything else. Similarly, the substantial utility of the CD player cannot be that it can be used as a doorstop since many objects can equally be used as a doorstops. A credible utility is one that would be believable toby someone in the field of research based on evidence supplied. This means that there must be some basis in published material or in general knowledge in the field that would lead someone to conclude that the claimed utility could actually be true.

Overall, the US guidelines suggest an approach that demands something more than a mere assertion of utility but less than proof that the invention will, in fact, be useful. So, for example, while an inventor cannot merely claim that the invention is useful without some support in the literature or evidence supplied by the inventor, the inventor has no obligation to prove that the invention can, as described, actually serve a useful purpose. This is because it is sufficient to meet the utility standard if a person could reasonably believe that the invention could work (that is, the utility is credible). Since the

patent office must resolve any doubts in favour of granting a patent, the US utility standard takes a middle-ground approach.

The administration of patents in Europe is bifurcated. The European Patent Office has the ability to grant patents throughout Europe, while national patent offices can also grant patents within their particular countries. The general utility standard in Europe (called industrial application) is that an invention can be manufactured or have some plausible industrial use. The European Patent Office states that this standard is low. Any activity that belongs to the useful or practical arts, as opposed to the aesthetic arts, is sufficient to meet the utility requirement in Europe. In fact, the European Patent Office states that very few inventions will be found wanting for utility provided that the inventions areis otherwise patentable. The same basic approach exists within individual European countries. They too impose a low threshold for utility.

To better understand the differences between the approaches taken to utility in the United States and in Europe, consider the following situation. A researcher identifies a sequence of 30 nucleotides (individual codes in the DNA). The researcher knows that this sequence belongs to a gene within a plant, but does not know which one or what the protein produced from that gene does. The researcher states that the sequence is useful because it can be used to identify the function of the gene within particular cell types. Assume further that the sequence is new and non-obvious. In the United States, the sequence would not be patentable (this is made clear under the new guidelines) because it lacks a substantial utility. That is, the sequence does not perform any substantial task, since identifying a gene of unknown function is not very useful. On the other hand, the European Patent Office as well as

the national patent offices in Europe, would likely find that invention had a sufficient industrial application.

The situation in Europe may change in light of the European *Directive on the legal protection of biotechnological inventions (*the *Directive)* . This *Directive* required that by July 30, 2000, Member States of the European Union modify their laws with respect to the patenting of biotechnological inventions in accordance with the *Directive.* The *Directive* states that genes, DNA sequences, and proteins are clearly patentable provided that these substances meet the general requirements of novelty, non-obviousness, and industrial application. The *Directive* also indicates , however, that, in respect of human genetic sequences, an inventor must indicate the function of the sequence (presumably the protein for which it codes and possibly the function of that protein) in order for it to be considered to have an industrial application. This is stated, however, in non-binding recitals and is only obliquely carried forward into the binding text of the *Directive.* Given this lack of clarity and the fact that the *Directive* is silent on the application of the industrial application standard to genes of non-human origin (presumably, even if identical to a human gene), the exact effect that the *Directive* will have on the application of this standard in Europe is uncertain. So far, the European Patent Office has not indicated any change in the industrial application standard.

Canada appears to apply a standard similar to that described in the new United States utility guidelines. The Canadian Intellectual Property Office states that an invention must have an actual, ultimate utility in order to meet the utility standard. An ultimate utility seems to be similar in concept to a real-life or substantial utility in the United States while an actual utility seems to be similar in nature to US concept of credible utility. The Canadian guidelines are far less detailed and clear than those ofin the

United States, so it is difficult to compare the standards outright. But the general approach taken in Canada is that a DNA sequence can only be patented if it has an evident (to one skilled in the art) or described function.

Additional Limits on Gene Patenting

The mere fact that a gene or DNA sequence meets the patent criteria of novelty, non-obviousness, and utility does not automatically lead to the grant of a patent. The inventor of that gene or sequence must first file a patent application with the appropriate patent offices around the world and those patent offices must review the application and, eventually, issue the patent. This procedure leads to two additional limits on gene patenting. The first is the cost of patenting a gene or sequence. The second is the availability to patent offices of reasons to withhold a patent despite the meeting of the novelty, non-obviousness, and utility requirements. I will discuss each of these limits in turn.

Patent prosecution—the procedure of preparing and filing a patent application and following-up with patent offices until the patent is issued—takes time and money to accomplish. As a rough figure, it costs at least $10,000 to prosecute one patent application in one country. Since inventors, especially in the biotechnology field, often file patent applications in many countries around the world, the costs of fully prosecuting one patent internationally can easily exceed $100,000. Although there are international procedures to streamline the process of getting patents around the world (for example, the *Patent Co-operation Treaty*), patents must still be translated into local languages and local patent offices must be satisfied. Cost is, therefore, a significant barrier to patenting genes and DNA sequences. This means that it will generally not pay to patent genes and sequences unless either

the cost per gene or sequence can be reduced or if the inventor has reason to believe that the particular gene or sequence is commercially valuable.

One way to reduce the cost per gene or DNA sequence is to include many genes or sequences in a single patent application. This way the $10,000 cost per country is divided betweeny many genes and sequences, making the process more commercially reasonable. Patent offices around the world have greeted this effort at cost-reduction with some hesitation. Not only does the inclusion of multiple genes and DNA sequences in a single patent application make it more difficult for patent offices to recover their costs of reviewing the patent (the United States Patent Office is designed to be self-supporting on the basis of fees charged), but it encourages people to patent genes on a speculative basis since the opportunity cost of doing so is low.

In reaction to the trend ofto attempting to claim multiple gene and DNA sequences in a single patent application, some patent offices have imposed limits on the number of genes and sequences that a single application may contain. The United States Patent Office has limited the number of independently claimed genes and sequences (genes and sequences that are not related) to ten. The European Patent Office will not allow an inventor to claim more than one independent gene or sequence within a single application. The Canada Intellectual Property Office (CIPO) has not set any limit on the number of independent genes and DNA sequences that a single patent application may contain. Nevertheless, CIPO requires, as do its counterparts in Europe and the United States, that the sequences be unified in some manner. Therefore, an application could not include completely unrelated gene sequences in one application.

The second limit on gene and DNA sequence patents consists of the ability of a patent office to reject a patent application that otherwise meets the novelty, non-obviousness, and utility requirements because the patent itself or, more precisely, the commercial use of that patent, would violate public order (Aordre public@)[5] or morality. A patent that violates public order would be one where the commercial use of the patented invention causes significant public unrest and political disorder. Morality means generally accepted moral norms within the particular society. For example, patents that cover embryos that are likely to grow to term areis often thought to violate morality. How this exception would apply, if at all, to gene sequences, has not be determined.

[5]See *supra* note 1.

The European Patent Office, as well as national patent offices within Europe and Asia, are ablehave the ability to reject patents on this basis while those in the United States, Canada, and Australia, for example, do not. The debate between these two groups of countries is not so much whether public order or morality are important;: it is whether it is best to incorporate consideration of public order and morality at the patent-granting stage or subsequently, through targeted legislation.[6] The Europeans believe, for example, that it is important to withhold patents over inventions which ought not to be commercialized in order to safeguard important public policy concerns. The position of the United States and Canada is that patent offices do not have the expertise to evaluate public policy goals; these goals are best left to legislatures and regulatory bodies. After all, this position holds, simply because someone holds a patent does not necessarily mean that he or she can use it. That person will still need to comply with existing laws and regulations to the extent these exist. The Europeans believe, on the other hand, that by incorporating public policy concerns within the patent process, there is no need for legislation and regulation to constantly Acatch-up@ with fast moving developments in biotechnologyBsomething that is very difficult to do.

[6]See, for example, M. Hirtle & B.M. Knoppers, *Banking of Human Materials, Intellectual Property Rights and Ownership Issues: International Policy Positions and Emerging Trends in the Literature* (Ottawa: Intellectual Property Policy Directorate, 1998).

Patent Policy Issues

In addition to mooting the possibility of introducing a public order and morality clause into patent law, commentators have raised more particular public policy concerns. These include, but are not limited to, the following:

1) that those who provide samples of their DNA have given fully informed consent to the use of that DNA;

2) that the blood relatives of those who gave DNA samples give appropriate informed consent to the use of their relatives DNA;

3) that the financial and other benefits arising out of the gene or sequence patent is equitably shared among industry, researchers, and the communities from which the human, animal, or plant samples derived;

4) that the public will have adequate access to the products of basic genetic research;

5) that an appropriate balance be struck between research directed at preventing disease, research aimed at diagnosing disease, and research aimed at treating disease;

6) that we adequately consider the needs of the developing world, especially with respect to agriculture;

7) that we appropriately balance public sector and private sector research in biotechnology and health care in general;

8) that we ensure the protection of the environment; and

9) that we provide inventors with an adequate financial incentive to invent without creating so many patents that present and future researchers find it financially and logistically impossible to undertake the next stage of research.

Instead of analysing each of these concerns independently and in depth, I will highlight some of the common elements running through them. The first two concerns relate to those individuals, and the populations in which they exist, who provide samples of their DNA for research purposes. There is an ethical concern that these individuals ought to understand what they are providing to the researchers and how their DNA may be used.[7] They should also understand that, in the course of their work, the researchers may discover that the individual involved has a genetic mutation that may be linked to a higher incidence of contracting a particular disease. These individuals should be told whether the researchers will inform individuals of these results and whether anyone else will have access to the information. In addition, because genes are shared among blood relatives, we must also be concerned about the creation of unwanted genetic information related to those blood relatives. There has been some controversy, for example, in the United States, over whether researchers need to explicitly get the consent of close family members before taking and using DNA samples.[8] Similar questions of consent, albeit at the community level, exist with respect to animals and plants originating in particular countries.[9]

---

[7]The European *Directive on the legal protection of biotechnological inventions* addresses the issue of informed consent in recital 26. See B.M. Knoppers, M. Hirtle & K.C. Glass, ACommercialization of Genetic Research and Public Policy@ (1999) 286 Science 2277.

[8]M. Wadman, AGeneticists oppose consent ruling@ (2000) 404 Nature 114.

[9]See article 15 of the United Nations Conference on Environment and Development Convention

on Biodiversity, 5 June 1992, 31 I.L.M. 818 that states as follows:

> 1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.
> 2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.
> 3. For the purpose of this Convention, the genetic resources being provided by a

Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.

4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.

5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.

7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Second, we must also consider whether it is appropriate for industry to share the proceeds of its inventions with the populations from which the DNA samples were taken. For example, in Iceland, a company investigating the genetic background of the Icelandic population has agreed to provide an updated electronic database of health information to the government and to ensure that any new drugs or therapies developed using the genetic information will be available without charge to Icelanders.[10]

[10]B.M. Knoppers, ASovereignty and Sharing@ in T.A. Caulfield & B. Williams-Jones, eds., *The Commercialization of Genetic Research: Ethical, Legal, and Policy Issues*. (New York: Kluwer Academic/Plenum Publishers, 1999) at 1.

The next set of public policy concerns relates to the creation and implementation of overall health policy within the country. The principal use of human genetic information is, not surprisingly, use in health care. Given the importance of this sector not only to the economy, but to the community in general, there is concern that the introduction of patents over genes and DNA sequences will curtail or upset current health policy. For example, some have expressed concern that these patents will skew research away from finding and implementing new public health measures in favour of the development of more profitable therapies and diagnostics.[11] That is, patents may upset the appropriate balance between preventing and curing disease. This concern is part of larger questions over the creation of health policy goals and the roles of both industry and the public sector in formulating those goals.[12]

Finally, once we have ensured that those who give their DNA to researchers have been protected and that we have developed sound health policy goals that take into account the eaffects of gene and DNA sequence patents, we must take care to prevent these patents from clogging-up future

---

[11]E.R. Gold, AMaking Room: Reintegrating Basic Research, Health Policy, and Ethics into Patent Law@ in T.A. Caulfield & B. Williams-Jones, eds., *The Commercialization of Genetic Research: Ethical, Legal, and Policy Issues* (New York: Kluwer Academic/Plenum Publishers, 1999) at 63.

[12]*Ibid*.

research. One of the principal goals of patent law is to encourage innovation through the grant of limited monopolies to those who have successfully invented. For this strategy to work, the incentive, in the form of the monopoly, must be strong enough to motivate people to conduct research. At the same time, the monopoly must not be so strong that it becomes difficult for present and future researchers to take the next step in scientific development.

This balancing between too long and too short monopolies is particularly difficult with respect to gene and DNA sequence patenting. This is because genes and DNA sequences usually represent only the very first stages of research with respect to a disease. Much more research is required to turn these genes and sequences into preventative techniques, therapies, and diagnostics. The fear among biotechnology researchers is that, as patents over genes and sequences become more common, it will become more and more expensive (since rights to use the patented genes and sequences will cost money) and more and more logistically difficult (because the researcher must spend time negotiating for the use of patented genes and sequences) to conduct these next and necessary stages of research.[13] One pilot study has already indicated, for example, that almost half of research

[13]Heller, M.A. & Eisenberg, R.S. ACan Patents Deter Innovation? The Anticommons in Biomedical Research@ 280 Science 698 (1998).

laboratories conducting research on genetic testing have ceased to pursue research due to patents over the underlying genes or DNA sequences.[14]

[14]Cho, M. K., AEthical and Legal Issues in the 21st Century@ in *Preparing for the Millennium: Laboratory Medicine in the 21st Century, December 4-5, 1998,* 2nd ed. (Washington, D.C.: AACC Press, 1998).

While work continues, several commentors have suggested ways both within and external to patent law to deal with some of these public policy concerns. These suggestions must be evaluated not only on their likely impact on those concerns but on limitations imposed by international trade and international patent law. Suggestions include the following: imposing liability on patent holders for certain ethical breaches;[15] including a morality clause into Canadian patent law;[16] granting patents only on processes to isolate genes and not on the genes themselves;[17] making the utility standard more rigorous by requiring patent applicants to have even better knowledge of the function of the gene or sequence within the body;[18] limiting the number of genes and sequences that can be included in a single Canadian patent; broadening and clarifying Canada=s experimental use exception to permit researchers to conduct more research on patented genes and sequences without breach of the patent;[19] restricting

[15]T.A. Caulfield & E.R. Gold, AGenetic testing, ethical concerns, and the role of patent law@ (2000) 57 Clinical Genetics 370.

[16]B.M. Knoppers, M. Hirtle & K.C. Glass, ACommercialization of Genetic Research and Public Policy@ (1999) 286 Science 2277.

[17]R.P. Merges & R.R. Nelson, AOn the Complex Economics of Patent Scope@ (1990) 90 Colum. L. Rev. 839.

[18]B.M. Knoppers, AStatus, sale and patenting of human genetic material: an international survey@ (1999) 22 Nature Genetics 23.

[19]E.R. Gold, AMaking Room: Reintegrating Basic Research, Health Policy, and Ethics into Patent Law@ in T.A. Caulfield & B. Williams-Jones, eds., *The Commercialization of Genetic Research: Ethical, Legal, and Policy Issues* (New York: Kluwer Academic/Plenum Publishers, 1999) at 63.

patents to entire genes rather than components of genes;[20] and preventing anti-competitive licensing practices for the use of genes and sequences.[21]

Relationship Between Gene Patenting and Patenting of Higher Life Forms

The Canadian Intellectual Property Office does not currently grant patents in higher life forms**B**plants and animals other than uni-cellular organisms, and possibly their components. This may change depending on the resolution of a court case now under consideration by the Supreme Court of Canada.. In that case, an inventor is seeking patent protection over a genetically-engineered mouse. Patent offices in the United States and in Europe have already granted a patent over this mouse.

While the debate over the patenting of higher life forms continues in Canada, it is worth pausing to examine the inter-relationship between gene patents and patents over higher life forms. In the case of the genetically-engineered mouse, for example, the inventor did receive a patent over the gene inserted into the mouse even though the mouse itself was held to be unpatentable. I will briefly examine

---

[20] *Ibid.*

[21] *Ibid.*

to what degree patents in underlying genes provide inventors of higher life forms with exclusively rights to those life forms.

A person who holds a patent in a gene in isolated form can effectively prevent others from selling, transferring, or reproducing that gene through the use of technology. Someone wishing to create a genetically-modified plant or animal out of this gene will need access to the that gene in isolated form in order to insert copies of the that gene into the desired plant or animal cells. Therefore, by controlling the use and sale of the underlying gene, the patent owner can effectively prevent others from creating a genetically-modified plant or animal. Once a genetically-modified plant or animal is created and is purchased by someone, the patent over the underlying gene could not be used to prevent further reproduction of that animal or plant. That is, if Company A holds a patent over gene X in isolated form, Company A can prevent the use of gene X to create plant Y. Once, however, Farmer B grows plant Y, Farmer B can collect the seeds from plant Y and use them to grow new plants.

There is, however, one way for the gene patent owner to extend his or her control over the resulting genetically-modified plant or animal. If the patent owner creates or permits someone else to create a genetically-modified plant or animal using the patented gene, the patent owner can license the use of the plant or animal to farmers rather than selling it. If the patent owner licenses, rather than sells, the plant (or a seed for the plant) or animal, the patent owner is able to place conditions on the use of the plant or animal, such as that the farmer promises not to reproduce it. Then, if the farmer attempts to reproduce the plant or animal, he or she will be in breach of contract. The patent owner may also attach other conditions to the licencse, such as that the farmer use certain products or do certain things required by the patent owner.

Giving a licencse over the use of a plant or animal based on a gene patent is more complicated and risky than an outright sale of a plant or animal under a plant or animal patent. It is risky in the sense that if a plant or animal escapes and is innocently reproduced, then the inventor can no longer use his or her gene patent to prevent further reproduction of that plant or animal. Nevertheless, licencses can be fairly effective in securing for the gene patent holder benefits similar to thosethat of a patent over the plant or animal itself. There are two possible problems with this route, although neither has yet materialised. The first is that this practice could possibly be considered an abuse of patent rights under section 65 of the *Patent Act*. If this turns out to be the case, the Commissioner of Patents has various powers under section 66 of the *Patent Act*, including giving farmers a licencse to use the seeds without restriction. The second is that, in addition to abuse of patent rights, these licensing practices could potentially be a violation of the *Competition Act*.

Conclusion

Gene and DNA sequence patents have created much discussion and confusion among those interested in issues such as strengthening the biotechnology industry, protecting the environment, and ensuring a strong health care system. Under current patent laws in Canada and elsewhere, genes and sequences are patentable provided that they are new, non-obvious, and useful. There has not yet developed a consensus among countries over the proper application of the utility standard. Canada, like the United States under its new guidelines, requires that there be a concrete commercial use forto the gene or sequence before a patent will issue.

There are clearly are important public policy issues arising out of gene patenting. Some of these concern patent law itself and some are more general, relating to health care policy, agricultural policy, protection of the environment, and ethical treatment of DNA donors. While commentors have suggested ways both within and external to patent law to address these policy concerns, so far none of these suggestions has been implemented.